



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2013-0244; FRL-10818-01-OCSP]

Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment

Addendum for Ethylene Oxide; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of and solicits public comment on EPA's proposed interim registration review decision and draft risk assessment addendum for ethylene oxide.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2013-0244, through the *Federal eRulemaking Portal* at <https://www.regulations.gov>.

Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: The Chemical Review Manager for ethylene oxide as listed in table 1.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental and human health advocates; distributors and users of

medical devices; owners and operators of commercial sterilization facilities; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for ethylene oxide identified in table 1 in unit IV.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at: <https://www.epa.gov/dockets/commenting-epa-dockets>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to ethylene oxide (EtO) discussed in this document, compared to the general population.

II. Background

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed a proposed interim decision and draft risk assessment addendum for ethylene oxide (table 1). Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

III. Authority

EPA is conducting its registration review of ethylene oxide pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What action is the Agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's proposed interim registration review decisions for ethylene oxide and the draft risk assessment addendum and opens a 60-day public comment period on these documents.

Table 1. Ethylene oxide Registration Review Docket Details

Registration Review Case Name and Number	Docket ID Number	Chemical Review Manager and Contact Information
Ethylene oxide Case Number 2275	EPA-HQ-OPP-2013-0244	Jessica Bailey <i>OPPethyleneoxideinquiries@epa.gov</i>

The registration review docket for a pesticide includes earlier documents related to the

registration review case. For example, the review opened with a Preliminary Work Plan, for public comment. A Final Work Plan was placed in the docket following public comment on the Preliminary Work Plan.

The documents in the docket describe EPA's rationales for conducting additional risk assessments for the registration review of ethylene oxide, as well as the Agency's subsequent risk findings and consideration of possible risk mitigation measures. The proposed interim registration review decision is supported by the rationale included in those documents. Following public comment, the Agency will issue an interim or final registration review decision for ethylene oxide.

The registration review final rule at 40 CFR 155.58(a) provides for a minimum 60-day public comment period on all proposed interim registration review decisions. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the proposed interim decision. All comments should be submitted using the methods in **ADDRESSES** and must be received by EPA on or before the closing date. These comments will become part of the docket for ethylene oxide. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and may provide a "Response to Comments Memorandum" in the docket. The interim registration review decision will explain the effect that any comments had on the interim decision and provide the Agency's response to significant comments.

Background on the registration review program is provided at:
<https://www.epa.gov/pesticide-reevaluation>.

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 28, 2023.

Anita Pease,

Director, Antimicrobials Division, Office of Pesticide Programs.

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